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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,676	01/04/1999	DAVID WALLACH	WALLACH=21	8997

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/155,676	WALLACH ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16,20-22,43,44,46,47,49,50,53-60,62-71,73-75 and 77-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-16,21,47,55,62-64,70 and 71* is/are allowed.

6)☒ Claim(s) *22,43,44,46,49,50,53,54,56-60,65-69,73-75 and 77-79* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 13-16, 20-22, 43-44, 46-47, 49-50, 53-60, 62-71, 73-75, 77-79 are presently pending.

Claim Rejections - 35 USC § 112-1st paragraph

3. Claims 22, 43-44, 46, 49-50, 53-54, 59-60, and 65-69, 73-75, 77-79 are/remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 9-05-02, and those set forth in the Official Action mailed 6-27-03.

4. Applicant's arguments filed 8-17-07 have been fully considered but are not persuasive. Applicants traverse the instant rejection by means of amending the claims. Specifically Applicants argue that the present claims as amended no longer read on fragments, and thus Applicants requested reconsideration and withdrawal of this rejection. Claim 69 as amended now recites the following:

69 (Currently Amended). An isolated polypeptide that binds to TRAF2, said polypeptide:
a) comprising the amino acid sequence of SEQ ID I NO: 2, the amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:6, or the amino acid sequence of SEQ ID NO:5;
b) comprising ***an amino acid sequence*** of an analog of a), having no more than ten changes in the amino acid sequence of a), each said change being a substitution, deletion or insertion of an amino acid, which analog binds to TRAF2; or

c) comprising a derivative of a) or b) by modification of a functional group which occurs as a side chain or an N- or C-terminal group of one or more amino acid residues thereof without changing one amino acid to another of the twenty commonly occurring natural amino acids, which derivative binds to TRAF2.

Contrary to Applicant's assertions, to the extent that it remains that instant claim 69 recites the phrase "***an amino acid sequence of an analog***," it remains that the scope of instant claim 69(b) reads on an isolated polypeptide comprising an undefined amino acid sequence fragment of an analog of (a), wherein said analog maintains the ability to bind to TRAF2. All claims, depending from claim 69, and read on an isolated polypeptide comprising "an amino acid sequence of an analog" are now included in this rejected.

Furthermore, in regards to newly amended claim 53, the scope of this claim as presently amended now encompasses fragment language. Claim 53, part (b) now encompasses an isolated polypeptide comprising *an amino acid sequence of an analog,* wherein said analog binds TRAF2. All claims, depending from claim 53, and read on an isolated polypeptide comprising "an amino acid sequence of an analog" are now included in this rejected. (Applicant's amendment necessitated this rejection.) As stated in the prior office action, the specification as filed at paragraphs [0206]-[0207] teach only two forms of the NIK protein that are capable of binding to TRAF2. Specifically, the full length NIK protein was disclosed as binding to both the C-terminal and N-terminal regions of the TRAF2 protein, and the partial NIK clone (NIK 624-947) binds only to the C-terminal region of the TRAF2 protein. There are no other examples in the specification as filed, which describe the amino acid structure of partial clones of NIK, or analogues, or derivatives thereof, that function to bind TRAF2.

Applicant's arguments do not take the place of evidence that Applicant's were in possession of the full scope of the claimed invention at the time of filing of the instant application.

Furthermore, in regards to amended claim 60, it remains that its scope is not adequately described by the specification as filed. Claim 60 as amended encompasses an antisense oligonucleotide consisting of a sequence complementary to a portion of or complementary to the entirety of the mRNA encoding ***an amino acid sequence*** encoded by nucleotide sequence of SEQ ID NO: 3, wherein said antisense oligonucleotide being capable of effectively blocking translation of said mRNA. It is noted that Applicants have not disclosed any antisense oligonucleotide structures capable of effectively blocking translation of mRNA encoding any amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 3.

Additionally, Applicant's amendment to claim 60 to add the phrase "or complementary to the entirety of the mRNA encoding a TRAF2-binding polypeptide...," is not supported by the specification as filed. The claim now encompasses an antisense oligonucleotide consisting of a sequence complementary to the entirety of the mRNA encoding the amino acid sequence of SEQ ID NO: 2 (a sequence of 604 amino acids), the mRNA encoding the entirety *an amino acid sequence* encoded by SEQ ID NO: 3, the mRNA encoding the entirety of SEQ ID NO: 5. Applicants did not point out where support for this amendment could be found in the specification as originally found.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 recites the following: A DNA molecule comprising an isolated DNA sequence selected from the group consisting of:

(i) a cDNA sequence comprising the nucleotide sequence of SEQ ID NO: 1;

(ii) a cDNA sequence comprising the nucleotide sequence of SEQ ID NO:6; and

(iii) a cDNA sequence comprising the nucleotide sequence of SEQ ID NO:4,

7. Claim 56 recites a DNA molecule in accordance with claim 55, wherein said DNA sequence comprises the nucleotide sequence of SEQ ID NO:I or SEQ ID NO:4. The phrase "wherein said DNA sequence comprises the nucleotide sequence of SEQ ID NO:I or SEQ ID NO:4," lacks sufficient antecedent basis since the DNA sequence is selected from a group consisting of cDNA sequences comprising the nucleotide sequences of SEQ ID NO: 1, 6, and 4. The use of the term cDNA sequence in claim 55 indicates that the sequence is free of any intron sequences. Therefore, since claims 56 and 57 (which recites "DNA sequence comprises the nucleotide sequence of SEQ ID NO:3") do not make any mention of the cDNA sequence comprising the nucleotide sequence of SEQ ID NO: 1, 6, or 4, as they relate to the sequence of the "DNA sequence" recited in claim 55, the scope of claims 56-57 lack sufficient antecedent basis with the scope of claim 55.

8. Claim 58 recites the phrase: "wherein said DNA sequence comprises a DNA sequence encoding the polypeptide encoded by the DNA sequence of SEQ ID NO:6 (protein NIK of SEQ ID NO:7))." Claim 55 does not provide sufficient antecedent basis for the scope of this phrase as it is recited in claim 58.

Claim Rejections - 35 USC § 102

9. The rejection of claim 60 under 35 U.S.C. 102(e) as being anticipated by McElroy et al. is withdrawn in response to Applicant's amendment and arguments filed 8-17-07.

10. Claim 60 is rejected under 35 U.S.C. 102(e) as being anticipated by Gill et al. (US Patent No. 5,804,412).

11. Gill et al. discloses an oligonucleotide or 30 base pairs (see SEQ ID NO: 17 of Gill et al.) in length that is 100% complementary to a portion of mRNA encoding a TRAF2-binding polypeptide comprising *an* amino acid encoded by the nucleotide sequence of SEQ ID NO: 3 of the instant application. Specifically, SEQ ID NO: 17 of Gill et al. is 100% complementary to nucleobases 2600-2629 of SEQ ID NO: 3 of the instant application.

Although the prior art does not teach that the disclosed oligonucleotide would function as an antisense molecule to effectively block translation of the claimed mRNA encoding a TRAF2-binding polypeptide according to the present invention, absent evidence to contrary since the oligonucleotide of Gill et al. has significant complementarity to SEQ ID NO: 1, it would also function to effectively form a DNA/RNA hybrid with the mRNA produced from SEQ ID NO: 3, activate RNAse H cleavage of the RNA portion of said hybrid, and thereby block translation of the mRNA.

Conclusion

12. Claim 13-16, 21, 47, 55, 62-64, and 70-71 are allowable over the prior art.

13. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE